

Message

From: Corona, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=18D86FB8269B4557B5D06622B3A941AF-CORONA, ELIZABETH]
Sent: 4/13/2012 6:20:17 PM
To: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Winner, Darrell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]; Karen Hammerstrom [Hammerstrom.KarenLNDU@usepa.onmicrosoft.com]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]
CC: Stella Spyropoulos [Spyropoulos.StellaLNDU@usepa.onmicrosoft.com]
Subject: Re: Update on Methanol Controls and Request for Correction
Attachments: ORD-12-000-5420 Methanol submission of WOE article (draft)_04.12.12_kdeener.docx; IRIS_TOX_METHANOL_EPRDEC2009[1].pdf; ORD-12-000-5420 Methanol submission of WOE article (draft)_04.12.12_kdeener v2.docx; ORD-12-000-5420 Rhomberg methanol article.pdf; ORD-12-000-5420 Methanol article copywrite clearance.pdf; ORD-12-000-5420 MI weight of evidence article submission.pdf; ORD-12-000-4949 Methanol (draft) v2.docx; RFC10005 Methanol Institute.pdf

Alex has reported back to me that per Bob K's instructions we should keep all three of these responses separate, but make sure they are consistent.

Regarding ORD-12-000-4949 **Deliberative Process / Ex. 5**

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have attached the revised draft response, specifically noting that it has been archived, and the pdf of the draft December 2009 methanol assessment for reference. If we do add a watermark, I will update the response to indicate that we've done so.



ORD-12-000-4949 IRIS_TOX_MET...
Methanol (draft) ...



Regarding ORD-12-000-5420, attached is the most recent version of NCEA's draft response to the MI's request for us to post an article on the old docket, as well as some supporting documents. Our deadline for responding to this request has been extended to April 20th. Please take a look at the attached draft and send your comments/edits to me by **COB Tuesday, April 17th**.



ORD-12-000-5420
Methanol submis...



ORD-12-000-5420
Rhomberg metha...



ORD-12-000-5420
Methanol article ...



ORD-12-000-5420
MI weight of evid...

Regarding the Request for Correction, attached is the RFC submitted by the MI. Once Lek signs and sends ORD's response to -4949 (above) we can use the text from that final response as the basis for this one.



RFC10005
Methanol Institut...

- Elizabeth

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Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

From: Elizabeth Corona/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/13/2012 10:19 AM
Subject: Update on Methanol Controls and Request for Correction

We have been granted an extension for ORD-12-000-5420 to April 20th. This is the letter in which the MI asked for us to post an article on the archived methanol docket.

At this point we have three separate, outstanding requests from the MI: ORD-12-000-4949 (for which we already uploaded a draft to CMS), MI's 2010 Request for Correction (which we proposed to combine with our response to -4949), and ORD-12-000-5420 (which Kacee circulated a draft for last night).

I spoke with Nathan and Alex and they're sorting out which of these responses Lek would like us to combine. Apparently Chuck Elkins from the MI has been calling Lek's office asking to schedule a meeting to discuss our responses, but Lek has said no and told him that we'll be sending our response shortly.

Alex said he will get back to me this afternoon to let me know what they want us to do. So, at this point I think we should wait until we hear back before spending any more time refining the draft Kacee circulated last night.

--

Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

From: Elizabeth Corona/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA
Cc: Lynn Flowers/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/13/2012 08:18 AM
Subject: Re: MI control on submitting article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

FYI - CMS won't let me submit another extension request, since we already asked for an additional week. Therefore, we should really try to get this uploaded today, if possible.

--

Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

From: Kathleen Deener/DC/USEPA/US
To: Elizabeth Corona/DC/USEPA/US@EPA
Cc: Lynn Flowers/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/12/2012 06:15 PM
Subject: Re: MI control on submitting article on Weight of Evedence for Methanol (Cancer) IRIS Assessment

I've revised the draft response to the MI based on my conversation with Norm this afternoon. If you have comments, please let me know tomorrow if possible. This is due soon, but Elizabeth is requesting an extension.



ORD-12-000-5420
Methanol submis...

Kacee Deener, MPH

Acting Communications Director / Program and Regulatory Support Lead

National Center for Environmental Assessment | U.S. EPA – ORD (Mail Code 8601P) | 1200 Pennsylvania Ave. NW | Washington, D.C. 20460

(ph) 703.347.8514 | (f) 703.347.8699; deener.kathleen@epa.gov

Physical and overnight delivery address: U.S. EPA North Potomac Yard N-7622 | 2733 S. Crystal Dr. | Arlington, VA 22202

From: Elizabeth Corona/DC/USEPA/US
To: Lynn Flowers/DC/USEPA/US@EPA
Cc: Kathleen Deener/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/12/2012 02:04 PM
Subject: Re: MI control on submitting article on Weight of Evedence for Methanol (Cancer) IRIS Assessment

FYI - We're in a bit of a stand still with the response to the previous control, waiting on Nathan and others to help us figure out if we can combine the response to the control with the RFC response. We should probably keep this one separate, since the requests were sufficiently different. But we definitely need to make sure the content is consistent.

Norm - Would you please let me know what you find regarding what we have already posted on the web?

In the mean time I'll follow-up with Nathan about the previous response. Then we can get together and coordinate.

- E

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Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

From: Lynn Flowers/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA
Cc: Elizabeth Corona/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/12/2012 08:17 AM
Subject: Re: MI control on submitting article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

Kacee et al: I appreciate figuring out how to load the paper on regulations.gov at this late date and that we COULD do that--but as you indicate, that venue is not current and it would be kind of weird to handle this that way. I like the proposal that you have and I think (Norm?) that this information is already on the web---e.g., that we are redoing the cancer assessment and a timeline will be available soon. We also have the same information in the IRIS agenda information that will hopefully go out soon. NI

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks--
Lynn

Lynn Flowers, PhD, DABT
Associate Director for Health
National Center for Environmental Assessment
Office of Research and Development
U.S. EPA

Mailing address:
1200 Pennsylvania Ave., NW (8601P)
Washington, DC 20460
Phone: 703-347-8537
FAX: 703-347-8699

Physical location:
Two Potomac Yard (North Building)
2733 S. Crystal Drive
Arlington, VA 22202

From: Kathleen Deener/DC/USEPA/US
To: Elizabeth Corona/DC/USEPA/US@EPA
Cc: Darrell Winner/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/11/2012 05:47 PM
Subject: Re: MI control on submitting article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

I'm looking at the draft response to the MI control, and I'm wondering if we should take a different approach. I saw that Karen sent around draft language to post on the website about developing a new draft methanol assessment in light of the decision about RI data.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

If we think it will be awhile before the methanol text goes on the web, then the approach in the draft response (post the study to the docket) seems fine.

Thoughts?

Kacee Deener, MPH

Acting Communications Director / Program and Regulatory Support Lead

National Center for Environmental Assessment | U.S. EPA – ORD (Mail Code 8601P) | 1200 Pennsylvania Ave. NW | Washington, D.C. 20460

(ph) 703.347.8514 | (f) 703.347.8699; deener.kathleen@epa.gov

Physical and overnight delivery address: U.S. EPA North Potomac Yard N-7622 | 2733 S. Crystal Dr. | Arlington, VA 22202

From: Elizabeth Corona/DC/USEPA/US
To: Darrell Winner/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Kathleen Deener/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA
Date: 04/09/2012 11:17 AM
Subject: MI control on submitting article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

Does anyone have comments/feedback on the attached draft response to the Methanol Institute?

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Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

-----Forwarded by Elizabeth Corona/DC/USEPA/US on 04/09/2012 10:51AM -----

To: Darrell Winner/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Kathleen Deener/DC/USEPA/US@EPA, Elizabeth Erwin/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA
From: Elizabeth Corona/DC/USEPA/US
Date: 04/04/2012 06:05PM
Cc: Stella Spyropoulos/DC/USEPA/US@EPA
Subject: MI control on submitting article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

Hi Everyone,

Attached is a draft response to a control that was only recently assigned to NCEA in CMS, even though it came in to the Agency back in February. Their incoming letter requested that we post an article online. Karen did some digging around to figure out how to respond to their request. I've tried to capture the directions we received from OGC in the attached response. Please forgive the third paragraph, the content of which is pasted below, my poor little brain is struggling right now.

Deliberative Process / Ex. 5

I would greatly appreciate it if you would take a quick look and send me your comments/edits. I need to upload our response to CMS by **COB Friday 4/6**.

Thanks, Elizabeth

(See attached file: ORD-12-000-5420 Methanol submission of WOE article (draft).docx)

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Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699

----- Forwarded by Alexis Lan/DC/USEPA/US on 02/13/2012 04:29 PM -----

From: Greg Dolan <gdolan@methanol.org>
To: IRIS HOTLINE@EPA, Bernard King/DC/USEPA/US@EPA
Cc: Paul Anastas/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, Kevin Teichman/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA
Date: 02/13/2012 04:25 PM
Subject: Methanol Institute Submits Article on Weight of Evidence for Methanol (Cancer) IRIS Assessment

IRIS Submission Desk:

Attached you will find an article set to appear in Regulatory Toxicology and Pharmacology authored by Dr. Lorenz Rhomberg of Exponent titled "Hypothesis-Based Weight-of-Evidence Evaluation of Methanol as a Human Carcinogen," which we are forwarding to you for submission to the docket for the Toxicological Review of Methanol (Cancer) under the Integrated Risk Information System. As acknowledged, this peer reviewed article was prepared with financial support from the Methanol Institute.

With the cancer portion of the methanol assessment currently on hold, we believe that this paper provides critical guidance for approaching a weight-of-evidence review of methanol's carcinogenicity. Further, at the recent National Academy of Sciences BEST meeting, NCEA Acting Director Becki Clark noted that the IRIS program is "moving toward a standardized weight of evidence characterization for all health assessments." Given this statement, and the announcement by IRIS Acting Director Vincent Cogliano that the Agency would host a workshop later this year to explore various weight-of-evidence approaches, we would encourage you to give very careful consideration to the analysis conducted by Dr. Rhomberg and his team as you reexamine the draft methanol cancer assessment.

In the interest of transparency, we request that you post this letter and the accompanying article on the NCEA webpage devoted to the methanol assessment. To that purpose, the Methanol Institute has arranged for a license agreement listing www.epa.gov as the posting web site (also attached).

Thank you for this additional opportunity to provide critical data to inform the IRIS Toxicological Review of Methanol (Cancer).

Gregory Dolan
Acting CEO
Methanol Institute
gdolan@methanol.org

124 South West Street

Suite 203
Alexandria, VA 22314 USA
(703) 248-3636

Penthouse Level
Suntec Tower Three
8 Temasek Blvd
Singapore 038988
+65 6866 3238

(See attached file: MI IRIS Submission 13 Feb 2012.pdf)

(See attached file: Gradient Final WoE Methanol Article.pdf)

(See attached file: EPA License for Gradient Article.pdf)[attachment "MI IRIS Submission 13 Feb 2012.pdf" deleted by Kathleen Deener/DC/USEPA/US] [attachment "Gradient Final WoE Methanol Article.pdf" deleted by Kathleen Deener/DC/USEPA/US] [attachment "EPA License for Gradient Article.pdf" deleted by Kathleen Deener/DC/USEPA/US] [attachment "ORD-12-000-5420 Methanol submission of WOE article (draft).docx" deleted by Kathleen Deener/DC/USEPA/US]